#10 Decl 11/20/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Robert KLEIN

Group Art Unit: 1632

Serial No.: 09/887,540

Examiner: Wilson, Michael C.

Filed: June 21, 2001

Attorney Docket No.: R-193

For: TRANSGENIC MICE CONTAINING LPR5 GENE DISRUPTIONS

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office Action mailed October 2, 2002, concerning the Examiner's restriction to the claims, Applicants hereby provisionally elect, with traverse, the claims of Group IV (claims 8 and 10), drawn to a non-human transgenic animal having a disruption in a low density lipoprotein-related protein 5 gene (LPR5) and methods of making a transgenic mouse having a disruption in a low density lipoprotein-related protein 5 gene.

As stated in MPEP 803.01, two criteria must be present for a proper requirement for restriction between patentably distinct inventions: 1) the inventions must be independent or distinct as claimed; and 2) there must be a serious burden on the Examiner if restriction is required.

The Examiner asserts that claims 1-16 are drawn to seven distinct subjects as follows: Group I (claims 1-3), drawn to a construct encoding LPR5, a selectable marker and a method of making the targeting construct; Group II (claims 1-4), drawn to a targeting construct comprising two nucleic acid sequences homologous to LPR5 and a selectable marker between the two sequences, and methods of making the targeting construct; Group III (claims 5-7 and 9), drawn to cells having a disruption in LPR5; Group IV (claims 8 and 10), drawn to a non-human transgenic animal having a disruption in a low density lipoprotein-related protein 5 gene (LPR5) and methods of making a transgenic mouse having a disruption in a low density lipoprotein-related protein 5 gene; Group V (claims 11 and 12), drawn to methods of identifying agents that

modulate the expression or function of LPR5 using a non-human transgenic animal; Group VI (claims 13 and 14), drawn to methods of identifying agents that modulate the expression or function of LPR5 using cells; and Group VII (claim 15), drawn to LPR5 modulators.

Applicant respectfully draws the Examiner's attention to the claims of Groups VI and VII. From the content of the claims, it appears that the Examiner intended claims 13-15 to be included in Group VI, and the omitted claim 16 to be included in Group VII.

The Examiner asserts that inventions of Groups I and II are patentably distinct because the construct of Group I can be used to express DNA encoding LPR5 while the construct of Group II can be used for preventing expression of LPR5, and therefore the structure and mode of operation for each construct is mutually exclusive. Applicants respectfully disagree with the Examiner's conclusion. Claims 1-4 recite a targeting construct comprised of a LPR5 gene, but vary in breadth or scope of definition. Further, Groups I and II are classified in the same class and subclass, and contain the same subject matter. Claims 1-4 are related to one another and a search and examination of these claims can be made without additional burden on the Examiner.

The Examiner further asserts that the inventions of Groups I and III are patentably distinct because the protocol and reagents for the construct and cells are materially distinct and separate. The Applicant disagrees with the Examiner's assertion, a separate search or examination that would seriously burden the Examiner. The Applicants disagree with the Examiner's conclusion. Any search or examination of the prior art conducted on one of these aspects would produce results that would encompass the targeting construct and cells. Thus, the additional burden of a separate search or examination would not be required.

The Examiner also asserts that the inventions of Groups I and IV are patentably distinct because the protocol and reagents for the construct and mice are materially distinct and separate. The Applicant disagrees with the Examiner's assertion. A separate search or examination of these claims can be made without serious burden on the Examiner.

Further, the Examiner asserts that the inventions of Groups I and V are patentably distinct because the protocol and reagents for the construct and the method are materially distinct and separate. The Applicant disagrees with the Examiner in that the claims of Groups I and V are related and a search or examination of these claims can be made without serious burden on the Examiner.

The Examiner also asserts that the inventions of Groups I and VI are patentably distinct because the protocol and reagents for the construct and the method are materially distinct and separate. The Applicant disagrees with the Examiner's assertion. The claims of Groups I and VI are related and therefore would not cause the Examiner serious burden to search or examine the claims of Groups I and VI.

The Examiner asserts that the inventions of Groups I and VII are patentably distinct because the protocol and reagents for the construct are materially distinct and separate from the agent. The Applicant disagrees with the Examiner's assertion. The claims of Groups I and VII are related and a search or examination on these claims would not seriously burden the Examiner.

The Examiner also asserts that the inventions of Groups II and III are patentably distinct. The Examiner contends that the claims of Group II are directed to an LPR5 knockout construct and the claims of Group III are directed to a cell with LPR5 knocked out. Applicants believe that a search or examination on these claims would not be a serious burden on the Examiner.

The Examiner further asserts that the inventions of Groups II and IV are patentably distinct. The Examiner contends that the claims of Group II are directed to an LPR5 knockout construct and the claims of Group IV are directed to a transgenic animal with LPR5 knocked out. Applicants believe that a search or examination on these claims would not be a serious burden on the Examiner.

The Examiner asserts that the inventions of Groups II and V are patentably distinct because the protocol and reagents for the construct of Group II and the method of Group V are materially distinct and separate. The Applicant disagrees with the Examiner's assertion in that the claims of Group II and V are related and a search or examination on these claims would not seriously burden the Examiner.

Another assertion is made by the Examiner that the inventions of Groups II and VI are patentably distinct because the protocol and reagents for the construct of Group II and the method of Group VI are materially distinct and separate and also that the construct of Group II does not require the method of Group VI and the method of Group VI does not require the construct of Group II. The Applicant disagrees with the Examiner's assertions in that the claims of Group II and the claims of Group VI are related and, therefore, a search or examination on these claims would not seriously burden the Examiner.

Additionally, the Examiner contends that the inventions of Groups III and IV are patentably distinct. The Examiner contends that the claims of Group III are directed to a cell having LPR5 knocked out and the claims of Group IV are directed to a transgenic animal with LPR5 knocked out. Applicants believe that a search or examination on these claims would not seriously burden the Examiner.

Further, the Examiner asserts that the inventions of Group III and V are patentably distinct because the cells of Group III are not required for the method of Group V and the method of Group V is not required for the cells of Group III. The Applicant disagrees with the Examiner's contention in that the cells of Group III are related to the method of Group V and a search or examination of these claims will not seriously burden the Examiner.

The Examiner further asserts that the inventions of Group III and VI are patentably distinct because the process can be used with transgenic animals and the product can be used to make transgenic animals. Applicants disagree with the Examiner's assertion in that the claims of Group III and VI are related. Therefore, a search or examination of these claims can be made without serious burden to the Examiner.

The Examiner also asserts that the inventions of Group III and Group VII are patentably distinct because the protocols and reagents for using the cells and the agent are materially distinct and separate. The Applicant disagrees with the Examiner's assertion in that the claims of Group III and VII are related and a search or examination on these claims will not seriously burden the Examiner.

The Examiner asserts that the inventions of Group IV are distinct from the invention of Group V because the process can be performed with cells *in vitro* and do not require the mice, and the mice can be used for the isolation of cells for *in vitro* assays. The Applicant disagrees with the Examiner's assertion in that the claims of Groups IV and V are related. A separate search or examination on the claims of Groups IV and V will not seriously burden the Examiner.

Further, the Examiner asserts that the Inventions of Groups IV and VI are patentably distinct because the mouse of Group IV does not require the method of Group VI and the method does not require the mouse. Applicant believes that a search or examination on these claims would not seriously burden the Examiner.

The Examiner also asserts that Groups IV and VII are patentably distinct because the protocols and reagent for the mouse of Group IV are materially distinct and separate from the

agent of Group VII. Applicants believe that a separate search or examination can be made without serious burden on the Examiner.

Additionally, the Examiner asserts that the inventions of Group V and Group VI are patentably distinct because the protocols for testing compounds *in vitro* and *in vivo* are materially distinct and separate. Applicant disagrees with the Examiner's assertion. The claims of Groups V and VI are related and a search or examination on these claims can be made without serious burden on the Examiner.

The Examiner also asserts that the inventions of Groups V or VI and VII are distinct. Applicant disagrees with the Examiner's assertion in that the inventions of Groups V, VI and VII are related and a separate search or examination can be made without serious burden on the Examiner.

Although the Applicant has provisionally elected Group IV for purposes of advancing prosecution of the present application, Applicant contends, for the foregoing reasons, that the restriction requirement is improper. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the requirement.

Respectfully submitted,

Date: 11-01-02

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Enclosures

CERTIFICATE OF MAILING UNDER 37 CFR 1.8

I hereby certify that this correspondence and its listed enclosures is being deposited with the United States Postal Service as First Class Mail, postage paid, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, Box NF Amendment on **November 1, 2002**

Name: **Deborah A. Mojarro**

Signed: Deborah Mojarro Date: 11/1/02